UNITED: STATES DISTRICT OF NEW YORK Filed 08/27/04 Page 1 of 87 PageID #: 1 EASTERN DISTRICT OF NEW YORK

GARY D. GOTLIN, as Public Administrator of The State of New York, in and for the County of Richmond, in his capacity as Administrator of the Estates of the following decedents:

GIUSEPPA CARAMANNA BONO, deceased, and her surviving spouse, GIUSEPPE BONO

DINO BROVELLI, deceased, and his surviving spouse, PATRIZIA SIRAGUSA BROVELLI;

DINO CATTAI, deceased, and his surviving spouse, VIRGINIA GRANDIN CATTAI;

FRANCESCO CENTORE, deceased, and his surviving spouse, MARIA MENSITIERI CENTORE;

GIUSEPPE DiGANCI, deceased, and his surviving spouse, MARIA RITA PULEO DiGANCI;

ROBERTO ETTORE, deceased, and his surviving spouse, CARMELA FRAMMARTINO ETTORE; and

MASSIMO FACCHINI, deceased, and his surviving spouse, FEDERICA LOSACCO FACCHINI; and

GIANCARLA PESCI; and ANTONIO RODA,

Plaintiffs,

-against-

GILBERT S. LEDERMAN, M.D.; GILBERT LEDERMAN, M.D., P.C.; PHILIP JAY SILVERMAN, M.D.; IRINA GROSMAN, M.D.; JOSEPH CONTE; SALVATORE CONTE; MARIA GELMI-NOURBAHA; ANNAMARIA PERSICO; STATEN ISLAND UNIVERSITY HOSPITAL; NORTH SHORE-LONG ISLAND JEWISH HEALTH CARE, INC.; NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC.; ANDREW J. PASSERI; ALFRED L. GLOVER; RALPH J. LAMBERTI; GERALD FERLISI; ANTHONY C. FERRERI; BETSEY MERCEREAU; RICK J. VARONE; JOSEPH R. PISANI; DALE TAIT; JOHN L. COSTELLO; JOHN A. D'ANNA; and JOHN M. SHALL,

Defendants.

FILED

N. GLERK'S OPPION

AUG 2 7 2004

BROOKLYN OFFICE

GLASSER, J.

MANN, M.J.

CVF 04 3736

COMPLAINT

JURY DEMANDED

The plaintiffs, by their counsel, BEHRINS & BEHRINS, P.C., complaining of the defendants,

allege as follows:

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 2 of 87 PageID #: 2 NATURE OF ACTION & PARTIES

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- 1. This is an action for compensatory and punitive moncy damages by reason of the defendants': (a) violations of §§349 and 350 of the New York State General Business Law, to wit, engaging in deceptive acts and practices and false advertising, the latter being a class A misdemeanor under New York State Penal Law §190.20; (b) fraudulent misrepresentations and fraudulent concealment of material facts (common law fraud), including a class E felony under New York State Education Law §6512, and a class A misdemeanor under New York State Education Law §6513(1); (c) unjust enrichment; (d) various forms of negligence; (e) breach of warranty; (f) medical malpractice; (g) failure to secure informed consent in violation of the New York State Public Health Law §2805-d; (h) intentional and unintentional acts leading to certain plaintiffs' pain and suffering and wrongful deaths and loss of consortium; (i) violations of 15 U.S. C §1125 (Lanham Act), to wit, the use in commerce of false or misleading representations of fact in commercial advertising; and (j) violations of 18 U.S.C.§1961 et seq. (RICO), to wit, engaging in a pattern of racketeering activity resulting in the defendants' egregious unjust enrichment.
- 2. The deceased plaintiffs represented by the New York State, County of Richmond Public Administrator were Italian nationals who visited the United States during various periods of time throughout the years 2002 to 2003 for medical treatment rendered by the defendant hospitals and physicians.
- 3. On August 23, 2004 Limited Letters of Administration were issued to the Public Administrator on behalf of the deceased plaintiffs, GIUSEPPA CARAMANNA BONO (who died on July 24, 2003), DINO BROVELLI (who died on November 17, 2003), DINO CATTAI (who died on

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 3 of 87 PageID #: 3 March 21, 2003), GIUSEPPE DIGANCI (who died on September 22, 2002), FRANCESCO CENTORE (who died on January 29, 2003), ROBERTO ETTORE (who died on February 20, 2003), and MASSIMO FACCHINI (who died on March 23, 2003), and who, during their lifetimes, were Italian nationals who visited the United States during the same period to receive medical treatment from the defendant hospitals and physicians. Their surviving spouses, hereinafter named, were and are Italian nationals who visited the United States with their spouses for the aforesaid treatment: GIUSEPPE BONO, surviving spouse of GIUSEPPA CARAMANNA BONO; PATRIZIA SIRAGUSA BROVELLI, surviving spouse of DINO BROVELLI; VIRGINIA GRANDIN CATTAI, surviving spouse of DINO CATTAI; MARIA MENSITIERI CENTORE, surviving spouse of FRANCESCO CENTORE; MARIA RITA PULEO DIGANCI, surviving spouse of GIUSEPPE DIGANCI; CARMELA FRAMMARTINO ETTORE, surviving spouse of ROBERTO ETTORE; FEDERICA LOSACCO FACCHINI, surviving spouse of MASSIMO FACCHINI.

- 4. The plaintiffs, GIANCARLA PESCI and ANTONIO RODA, were and are Italian nationals who visited the United States during the same period to receive medical treatment from the defendant hospitals and physicians.
- 5. At all relevant times herein, the defendant GILBERT S. LEDERMAN, M.D. (hereinafter "LEDERMAN") was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of the State of New York; and the defendant GILBERT LEDERMAN, M.D., P.C., a professional corporation organized under and pursuant to the laws of the State of New York, was an employee, servant, agent, representative partner

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 4 of 87 PageID #: 4 and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH CARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC.

- 6. At all relevant times herein, the defendant PHILIP JAY SILVERMAN, M.D. (hereinafter "SILVERMAN") was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of the State of New York.
- 7. At all relevant times herein, the defendant, IRINA GROSMAN, M.D. (hereinafter "GROSMAN") was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of the State of New York.
- 8. At all relevant times herein, the defendant, JOSEPH CONTE, was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of the State of New York.
- 9. At all relevant times herein, the defendant, SALVATORE CONTE, was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 5 of 87 PageID #: 5 STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and upon information and belief, was a resident of Naples, Italy.

- 10. At all relevant times herein, the defendant, MARIA GELMI-NOURBAHA, (herinafter "GELMI-NOURBAHA") was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of the State of New York.
- 11. At all relevant times herein, the defendant, ANNAMARIA PERSICO, (hereinafter "PERSICO") was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and upon information and belief, was a resident of Naples, Italy.
- 12. Upon information and belief, detendant STATEN ISLAND UNIVERSITY HOSPITAL (hereinafter sometimes, "SIUH") is a duly organized corporation existing under and by virtue of the laws of the State of New York, is presently doing business in the State of New York, with offices and places of business in Staten Island and Brooklyn, and the New York metropolitan area, and upon information and belief, is either a wholly owned subsidiary of, or joint venturer with, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE, INC.

- 13. Upon information and belief, defendant NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE, INC. (hereinafter sometimes, "NORTH SHORE-LIJ") is a duly organized corporation existing under and by virtue of the laws of the State of New York, and is presently doing business in the State of New York, and upon information and belief, owned, operated, managed, maintained and/or controlled SIUH, or was a joint venturer in healthcare with SIUH.
- 14. Upon information and belief, defendant NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC. (hereinafter sometimes, "NORTH SHORE LIJ SYSTEM") is a duly organized corporation existing under and by virtue of the laws of the State of New York, and is presently doing business in the State of New York, and upon information and belief, owned, operated, managed, maintained and/or controlled SIUH and NORTH SHORE-LIJ, or was a joint venturer with SIUH and NORTH SHORE-LIJ.
- 15. At all relevant times herein, the defendant, ANDREW PASSERI (hereinafter "PASSERI"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the former President and CEO of SIUH, and upon information and belief, was a resident of the State of New York.
- 16. At all relevant times herein, the defendant, ALFRED L. GLOVER (hereinafter "GLOVER"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 7 of 87 PageID #: 7 SYSTEM, INC., to wit, the Executive Vice President and COO of SIUH, and upon information and belief, was a resident of the State of New York.

- 17. At all relevant times herein, the defendant, RALPH J. LAMBERTI (hereinafter "LAMBERTI"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Executive Vice President of SIUH, and upon information and belief, was a resident of the State of New York.
- 18. At all relevant times herein, the defendant, GERALD FERLISI (hereinafter "FERLISI"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Senior Vice President and CFO of SIUH, and upon information and belief, was a resident of the State of New York.
- 19. At all relevant times herein, the defendant, ANTHONY C. FERRERI (hereinafter "FERRERI"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, President and CEO of SIUH, and upon information and belief, was a resident of the State of New York.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 8 of 87 PageID #: 8 20. At all relevant times herein, the defendant, BETSEY MERCEREAU (hereinafter "MERCEREAU"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Corporate Secretary of SIUH, and upon information and belief, was a resident of the State of New York.
- 21. At all relevant times herein, the defendant, RICK J. VARONE (hereinafter "VARONE"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the former President of SIUH, and upon information and belief, was a resident of the State of New York.
- 22. At all relevant times herein, the defendant, JOSEPH R. PISANI (hereinafter "PISANI"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTH CARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the former Executive Vice President of SIUH, and upon information and belief, was a resident of the State of New York.
- 23. At all relevant times berein, the defendant, DALE TAIT (hercinafter "TAIT"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 9 of 87 PageID #: 9 HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Vice President and Corporate Secretary of SIUH, and upon information and belief, was a resident of the State of New York.

- 24. At all relevant times herein, the defendant, JOHN L. COSTELLO (hereinafter "COSTELLO"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, Senior Vice President and CFO of SIUH, and upon information and belief, was a resident of the State of New York.
- 25. At all relevant times herein, the defendant, JOHN A. D'ANNA (hereinafter "D'ANNA"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Executive Vice President of SIUH, and upon information and belief, was a resident of the State of New York.
- 26. At all relevant times herein, the defendant, JOHN M. SHALL (hereinafter "SHALL"), was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendants STATEN ISLAND UNIVERSITY HOSPITAL, NORTH SHORE-LONG ISLAND JEWISH HEALTHCARE INC., and NORTH SHORE-LONG ISLAND JEWISH HEALTH SYSTEM, INC., to wit, the Chairman of the Board of Trustees of SIUH, and upon information and belief, was a resident of the State of New York.

- 27. This court has subject matter jurisdiction over the action pursuant to 28 U.S.C §1332 because the matter in controversy exceeds the sum of \$75,000.00 and the parties are citizens of different countries.
- 28. This court has subject matter jurisdiction over the action pursuant to the following statutes arising under the laws of the United States: 18 U.S.C.§1964 and 15 U.S.C.§1125.
- 29. This court has subject matter jurisdiction over the action pursuant to 28 U.S.C. §1367, and principles of pendent jurisdiction in that city, state and federal law claims arise from a common nucleus of operative facts.
- 30. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391, 15 U.S.C. §77v, 15 U.S.C. §78 aa, 18 U.S.C. §1965, and 7 U.S.C. §25(c).

FACTS AND ALLEGATIONS COMMON TO ALL COUNTS

FALSE ADVERTISING AND COMMON LAW FRAUD

- 31. In approximately late 2001/early 2002, defendants faunched an International Patient Program, whereby they targeted Europeans, and predominately Italian nationals, in Italy, for Fractionated Stereotactic Radiosurgery treatment for various types of cancer.
 - 32. The defendants, in their marketing kit, defined Fractionated Stereotactic Radiosurgery

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 11 of 87 PageID #: 11 as "... precision radiation using multiple, finely contoured beams from many different angles - all directed at the cancer, minimizing radiation to normal healthy tissue. A non-invasive stereotactic frame maintains the body in a stable, reproducible position. A stereotactic body frame secures this position which is painlessly and non-invasively custom-molded about the body."

- 33. The hospital and physician defendants, with the advice, consent, encouragement and complicity of the other defendants, rendered futile, unproductive, and ineffectual Fractionated Stereotactic Radiosurgery to hundreds of Italian nationals, including the plaintiffs herein, between 2001 and 2003.
- 34. Upon information and belief, in late 2003 or early 2004 Fractionated Stereotactic Radiosurgery treatment was suspended by the defendants.
- 35. The defendants, individually and acting in concert, promoted, marketed, and advertised their stereotactic radiosurgery treatment to Italian nationals in Italy, including the plaintiffs.
- 36. The defendants employed various media to promote, market, and advertise the stereotactic radiosurgery treatment throughout Italy and the United States, including, but not limited to, printed literature, television, radio, face-to-face seminars, and the Internet.
- 37. The defendants lured and enticed patients from the public at large, including the plaintiffs, by false, fraudulent and deceitful advertisements and misrepresentations, including representations that the radiosurgery treatment had "tremendous results" with extraordinary and enticingly high success rates for various forms of cancer.

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- 38. The defendants printed and disseminated by the mails and various electronic media written materials regarding their program, including the booklet "Fractionated Stereotactic Body Radiosurgery at Staten Island University Hospital."
- 39. The defendants made false and misleading statements in the electronically disseminated and other written materials to deceive the public at large and prospective patients, including the plaintiffs, and to entice them to participate in their stereotactic radiosurgery program at SIUH.
- 40. The defendants made the following misleading, fraudulent, deceitful, and shocking claims, statements, and information in their "Fractionated Stereotactic Body Radiosurgery" marketing booklet:

"Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery - 90 percent - arc successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."

"The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area - meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."

"Many patients were so-called 'hopeless cases' before coming to Staten Island University Hospital."

The booklet then continues with the following outrageous, misleading and false representations:

"Primary Liver Cancers: ... In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90 percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."

"Liver Metastases: ... We have a success rate of 88 percent ..."

"Primary Lung Carcinomas: ... The local control rate is 89 percent."

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 13 of 87 PageID #: 13 "Pulmonary or Lung Metastases: ... The local control rate is 88 percent. Many patients

"Pulmonary or Lung Metastases: ... The local control rate is 88 percent. Many patients come to us with severe lung disease not felt to be candidates for standard surgery or radiation."

"Primary Pancreas Cancers: Primary pancreas cancers have been treated with a very high rate of success. In fact, 94 percent of primary pancreas cancers currently have been successfully controlled in the treated area with Body Radiosurgery at Staten Island University Hospital. Many included patients who had extensive prior unsuccessful treatment ... Furthermore, the size of the cancers treated with Body Radiosurgery here was, on average, three times the size and still we had a dramatically higher success rate. Thus, our success rate locally for pancreas cancers is 94 percent."

"Other Abdominal Tumors: ... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as adrenal glands and pre-sacral metastases. The local control rate for adrenal tumors is 94 percent."

- 41. The plaintiffs also relied on the following misinformation disseminated by the defendants:
 - (a) "Our group of expert physicians has the greatest experience worldwide."
 - (b) "Staten Island University Hospital has led the way with refined development of noninvasive techniques for Fractionated Stereotactic Radiosurgery treating brain and body tumors. We have performed one hundred thousand radiosurgeries! Results are superior for many tumors—benign and malignant—with better maintenance of function, fewer complications and lesser need for subsequent intervention, in general."
 - (c) "Fractionated Stereotactic Radiosurgery...
 Often it can be used initially at the time of
 diagnosis and, if necessary, later, if
 standard surgery, chemotherapy or
 radiation has not been fully effective."
 - (d) "We have superb results in controlling targeted tumors even when normal radiation has not been successful..."

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- (e) "...higher doses of radiation can be delivered to the cancer with anticipation of greater success."
- (f) "Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery 90 percent are successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."
- (g) "The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area - meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."
- (h) "Indeed, more than one hundred thousand stereotactic radiosurgery procedures have been performed at Staten Island University Hospital over many years."
- (i) "Out CT simulator used for imaging is considered one of the finest worldwide to allow us better visualization of the cancer. Few centers have access to the technology we use daily."
- (j) "(Fractionated Stereotactic Radiosurgery) radiation will be much better tolerated with superior outcomes then standard therapy, even though we give higher treatment doses, when appropriate."
- (k) "The ultimate three-dimensional radiation - well beyond conformal or just intensity modulated inverse planning - is part of our daily armamentarium. Conformal radiation neither has this degree of

sophistication nor these results. Ours is a technique with which we are most comfortable and perform repeatedly every day and every night for patients who come from around the country and throughout the world."

- (I) "Data collected with thousands of procedures being performed continue to show marked efficacy for primary and metastatic cancer treatment. Frequently these cancers were considered to be untreatable by other modalities or to have treatment approaches that were much less promising."
- (m) "... but a vast array of types of cancers including adenocarcinomas, squamous carcinomas, lung cancers, breast cancer, germ cell tumors, primary liver tumors, pancreas tumors, colon cancers, sarcomas, melanomas, renal cell, metastatic and primary head and neck cancers and others have been successfully treated and are included in ongoing data evaluation."
- (n) "Many patients were so-called "hopeless cases" before coming to Staten Island University Hospital. Some come to Staten Island University Hospital insisting on Body Radiosurgery only - wishing not to receive any standard therapy."
- (o) "Body Radiosurgery has been successfully implemented over the years for hepatocellular and other primary liver cancers. Body Radiosurgery for primary liver tumors, such as hepatocellular carcinomas, cholangiocarcinoma and gall bladder cancers, have been treated with excellent control rates."
- (p) "In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90

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percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."

- (q) "Liver metastases are cancers that have spread to the liver from the other primary sites... We have a success rate of 88 percent."
- (r) "...primary lung cancers can be treated with this technique... Many patients with lung cancers have chronic pulmonary obstruction disease and thus limitation of respiratory function. Because stereotactic radiosurgery minimizes the adverse effects to the healthy normal lung, one anticipates a better outcome using our pinpoint precision technique... Body Radiosurgery can be used alone or in combination after external beam radiation to boost the radiation dose to enhance success of treatment. The local control rate is 89 percent."
- "Lung metastases are cancer nodules that **(**\$) have spread to the lung from other primary sites. Pulmonary or lung metastases have been treated with Body Radiosurgery across the spectrum in size ranging from the small to the large. Standard radiation offers little in this specific category. Most common origins include head and neck cancers, melanoma, renal cells, breast, sarcoma, gastro-intestinal, colon, pancreas, liver, germ cell cancers, thyroid, and other primaries. The local control rate is 88 percent. Many patients come to us with severe lung disease not felt to be candidates for standard surgery and radiation."
- (t) "Primary pancreas cancers have been treated with a very high rate of success. In fact, 94 percent of primary pancreas cancers currently have been successfully controlled in the treated area with Body Radiosurgery in comparison to infusion of

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radioactive P32 and found Body Radiosurgery superior... Thus, our success rate locally for pancreas cancers is 94 percent."

- (u) "In the abdominal cavity, we treat primary and metastatic cancers... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as the adrenal glands and presacral metastases. The local control rate for adrenal tumors is 94 percent."
- (v) "Many patients with cancers who cannot be treated successfully using standard therapy or those with cancers that have recurred despite standard chemotherapy, surgery or radiation may wish to inquire about Body Radiosurgery. Also, those wishing this innovative therapy as a boost radiation dose (after standard radiation) to increase chances of local control and overall success should be motivated to investigate Body Radiosurgery by contacting our physicians at Staten Island University Hospital."
- (w) "...Staten Island University Hospital has the ability to treat cancers extending from the head to the toe using sophisticated non-invasive techniques. These are the most advanced techniques worldwide."
- (x) "Those interested in Body Radiosurgery are asked to send relevant information, reports and pertinent radiographic studies - especially CT scans and/or MRI scans to our Radiosurgery Center for review."
- (y) "... 85 percent more men are cancer-free in our hands at SIUH than if they had radical prostatectomy ... at Johns Hopkins ... our results compare superbly to treatment at Harvard or University of Pennsylvania with radiation, radical prostatectomy or

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seeds alone - or with hormones ... there is a 77 percent disease-free survival at Staten Island University Hospital using combined seed/body radiosurgery. That is consistent with 157 percent improvement in outcome when treated at Staten Island University Hospital. Imagine the potential saving of lives."

- 42. The printed materials also falsely claimed that the highly successful treatment had minimal side effects.
- 43. Defendants translated these written materials into the Italian language and disseminated them by the mails and various electronic media to prospective Italian cancer patients.
- 44. Defendants also created and disseminated numerous videotaped advertisements regarding their Stereotactic Body Radiosurgery program both in English and in Italian, and disseminated them to the plaintiffs and the general public in Italy, other European countries, and the United States.
- 45. These videotapes/DVDs contained the same false, fraudulent and misleading information and representations in the printed sales packages, plus other reckless, wanton representations.
- 46. One of the videotapes, "Fractionated Stereotactic Body Radiosurgery," included the following false, fraudulent, misleading, and shocking claims, statements, and information by defendant LEDERMAN:
 - "... 90% success rate. Success means cessation of growth, shrinkage, or disappearance of the cancer. It's quick—each treatment takes thirty minutes or less and patients can go home and back to their normal activities very quickly after treatment. Many people call it a treat, not a treatment because of the effectiveness and the lack of toxicity in general."

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47. At all relevant times herein, defendant LEDERMAN was the Director of Radiation

Oncology for the defendant hospitals.

48. Defendants created and disseminated a videotape entitled "The Radiosurgery Center, Fractionated Stereotactic," which included the following false, fraudulent, misleading, and shocking claims, statements, and information:

"This new treatment is non-invasive, highly successful, and offers great hope to those who previously thought there was none."

"Tremendous results, results in many hopeless cases, people who thought there were no chances for them are coming, and many, many are having chances, another break at life."

"Tremendous results," "very high success rate," and a "90% success rate" are repeatedly touted claims.

- 49. Defendants used numerous false, misleading, and deceitful testimonials of other cancer patients in these videotapes to promote the stereotactic radiosurgery program.
 - 50. Defendants promoted their stereotactic radiosurgery program on Italian television.
- 51. The televised broadcasts contained the same false, fraudulent and misleading information to induce Italian cancer patients, including the plaintiffs, to leave Italy, abandon their treatment there, and undergo treatment by the defendants in Staten Island at SIUH.
- 52. In addition, defendants created and launched numerous internet websites regarding their Stereotactic Body Radiosurgery program, both in English and Italian.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 20 of 87 PageID #: 20 53. These internet websites contained the same false, fraudulent and misleading information to induce Italian cancer patients to leave Italy, abandon their treatment there, and undergo treatment by the defendants in Staten Island at SIUH.
- 54. The Italian interact websites also included application instructions directing prospective cancer patients to apply to the stereotactic radiosurgery program merely by sending a CT scan, a brief clinical history, a one-hundred Euro application fee, and miscellaneous information to defendant SALVATORE CONTE.
 - 55. The defendants preyed upon the plaintiffs' fears and hopes at their most vulnerable time.
- 56. The systematic dissemination of misinformation and promotion of false hope were designed to lure vulnerable cancer patients, including the plaintiffs herein, and their loved ones, to the defendants' stereotactic radiosurgery program in Staten Island.
- 57. That any reasonable prospective patient, including the plaintiffs, would rely on this false, misleading and described information and undergo the promoted stereotactic radiosurgery treatment.
 - 58. That the plaintiffs herein were in fact deceived and misled by the defendants.
- 59. That based upon the plaintiffs' reasonable reliance on the defendants' material misrepresentations, the plaintiffs herein were entired to leave Italy and undergo treatment by the defendants in Staten Island.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 21 of 87 PageID #: 21 60. In addition, defendants planned, advertised, organized, and conducted many promotional seminars and conferences throughout Italy, whereby the defendants reiterated the false, fraudulent, and deceitful information contained in the written materials and other media.
- 61. Defendants aggressively marketed their treatment program at these seminars and conferences to cancer patients in attendance with the same false, fraudulent, and deceitful information, and even implored them to take extra copies to distribute to other cancer victims and their families in their hometowns.
- 62. Defendants told prospective patients to bring their CT scans to the conferences for review by their agents, servants, and/or employees.
- 63. Defendant LEDERMAN spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the defendants' stereotactic radiosurgery treatment program.
- 64. Defendant SALVATORE CONTE spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the treatment program.
- 65. Defendant GELMI-NOURBAHA spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the treatment program.
- 66. Defendants held out defendant SALVATORE CONTE as a medical doctor and oncologist at the conferences.

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- 67. In fact, certain of defendants' televised broadcasts contained a subscript at numerous times while defendant SALVATORE CONTE is speaking, identifying him as a medical doctor and an oncologist.
- 68. Defendants provided defendant SALVATORE CONTE with business cards identifying him as a medical doctor and oncologist.
 - 69. That defendant SALVATORE CONTE was not a medical doctor, let alone an oncologist.
- 70. Defendants knew or should have known that defendant SALVATORE CONTE was neither a medical doctor nor an oncologist.
- 71. At the seminars and conferences, defendant LEDERMAN cursorily examined imaging films of different patients in attendance, including the plaintiffs, and told them and their families that he and the defendants could cure them.
- 72. Defendants telephoned the plaintiffs in Italy from the United States with oral instructions, and transmitted letters of "acceptance" to the plaintiffs, by mail and/or facsimile transmissions from the United States to Italy.
- 73. That when plaintiffs responded to the various media advertising by the defendants and/or attended the defendants' conferences, they were then directed to meet with defendant SALVATORE CONTE for processing and initial evaluation.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 23 of 87 PageID #: 23 74. Defendants established an office in Naples, Italy, for defendant SALVATORE CONTE, bearing an awning emblazened with the name Staten Island University Hospital Radiosurgery Center, to attract and process prospective patients.
- 75. Defendants paid for all expenses in establishing defendant SALVATORE CONTE's office in Naples.
 - 76. Defendants also employed defendant PERSICO to work in the Naples office.
- 77. Defendant SALVATORE CONTE held himself out to be a physician to render medical advice and opinions.
- 78. Defendant SALVATORE CONTE, holding himself out to be a physician, met with prospective patients, including the plaintiffs herein, and interviewed them, reviewed their CT scans, and advised them that they would be cured at the defendants' facilities in New York.
- 79. Defendant SALVATORE CONTE advised the plaintiffs and other patients that he was sending their CT scans and information to the defendants in Staten Island, purportedly for review and evaluation.
- 80. The defendants in New York, upon formally accepting prospective patients into their stereotactic radiosurgery program, sent these patients, including the plaintiffs, false and misleading information by facsimile and/or mail stating that their particular case was treatable.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 24 of 87 PageID #: 24 81. The defendants preyed upon the plaintiffs' fears and hopes at their most vulnerable time, when stricken with cancer.
- 82. The systematic dissemination of misinformation and promotion of false hope were designed to lure vulnerable cancer patients, including the plaintiffs herein and their loved ones, to the defendants' stereotactic radiosurgery program in New York.
- 83. The plaintiffs reasonably relied on the false, misleading and deceitful information to undergo the promoted Fractionated Stereotactic Radiosurgery treatment.
 - 84. The plaintiffs herein were in fact deceived and misled by the defendants.
- 85. Based upon the plaintiffs' reasonable reliance on the defendants' intentional, material misrepresentations, the plaintiffs were enticed to leave Italy and undergo treatment by the defendants in Staten Island, but the majority of the patients treated, including the deceased plaintiffs, died shortly after treatment, sometimes within weeks, sometimes within months.

■ GROSS, WANTON NEGLIGENCE ■

86. The defendants were careless, reckless, and otherwise grossly and wantonly negligent in failing to take reasonable care by not conducting a simple review to determine whether the representations made in their marketing media devices were accurate, knowing full well that the claims were made for the benefit and purpose of inducing other persons, including the plaintiffs, to rely thereon.

■ BREACH OF WARRANTY ■

87. The defendants, retained by the plaintiffs in reliance on the defendants' representations for

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 25 of 87 PageID #: 25 the predominant purpose of rendering services, to wit, Fractionated Stereotactic Radiosurgery, breached their express and/or implied warranties to cure or control cancer, thereby making the defendants strictly liable to the plaintiffs.

■GROSS, WANTON NEGLIGENCE IN EMPLOYMENT, SUPERVISION, AND RETENTION ■

- 88. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed, neglected, and/or refused to use reasonable care in the employment, training, supervision, and the retention of those defendants engaging in the marketing, selling, and administering of Fractionated Stereotactic Radiosurgery, in order to determine whether those defendants were competent to do their work and perform the treatments without danger of harm to others, in this case, the plaintiffs.
- 89. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed, neglected, and/or refused to conduct an investigation of the efficacy of administering of Fractionated Stereotactic Radiosurgery when the many deaths of patients soon after treatment, including the plaintiffs, would lead a reasonably prudent person to conclude that the treatment was contraindicated and should have been terminated.
- 90. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed and/or neglected to act prudently, their errors of commission and omission negligently resulted in scrious personal injuries and death to the plaintiffs.
- 91. The defendants were motivated by greed and bottom line profit objectives, and their intentional refusal to terminate timely the administration of Fractionated Stereotactic Radiosurgery resulted in serious personal injuries and death to the plaintiffs.

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UNJUST ENRICHMENT AND KICKBACKS *

92. Defendants charged each patient, including the plaintiffs herein, \$17,500.00 to enter the program, which said fee had to be paid in advance, and which did not include the plaintiffs' traveling expenses to and from Staten Island and Italy.

93. The defendants included with the aforementioned "acceptance letter" to the patients, including the plaintiffs herein, instruction sheets for payment, travel arrangements, and miscellaneous logistical information regarding the defendants' facilities in New York, which included a 10% payment (\$1,750.00) to be made directly to defendant SALVATORE CONTE's personal banking account by wire transfer.

- 94. The defendants negotiated this kickback with defendant SALVATORE CONTE as well as payment of his overhead expenses and office space in Naples, Italy, in consideration for his promise to meet defendants' quota for patients.
- 95. The kickback arrangement was discussed and approved at several meetings at the defendants' facilities in New York and/or in Italy among defendants consisting of at least LEDERMAN, SILVERMAN, GROSMAN, JOSEPH CONTE, SALVATORE CONTE, GELMI-NOURBAHA, and perhaps others.
- 96. The instructions also directed the patients, including the plaintiffs herein, to wire the balance of the charges to the defendant SIUH's operating account in New York.
 - 97. The patients, including the plaintiffs herein, did in fact wire the balance of the charges to

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 27 of 87 PageID #: 27 the defendant SIUH's operating account in New York.

- 98. In consideration of his efforts, the defendants also paid defendant LEDERMAN a set percentage of the monies received from the plaintiffs for their treatment, to wit, 20% (\$3,500.00) of the overall fee.
- 99. In some instances, the patients, including the plaintiffs herein, received instructions to wire a portion of the funds directly into defendant LEDERMAN's account in New York.
- 100. In some instances, the patients, including the plaintiffs herein, did in fact wire a separate sum into defendant LEDERMAN's account in New York.
- 101. Only upon full payment of the requisite fees could the patients, including the plaintiffs herein, be processed and scheduled for treatment.
- 102. The hospital defendants, upon information and belief, received gross annual fees between \$5,000,000.00 and \$10,000,000.00 during the period beginning in 2001 for radio therapy, including stereotactic body radiosurgery, and thereby were unjustly enriched.

■ MEDICAL MALPRACTICE AND HOSPITAL NEGLIGENCE ■ FAILURE TO SECURE INFORMED CONSENT ■

103. That as a result of the defendants' intentional dissemination of false, deceitful, and misleading advertising and unconscionable self-promotion, plaintiffs sustained injuries and damages, including bodily injury and death, psychological injury, monetary damages, lost opportunity for obtaining treatment and/or halting treatment in Italy, undergoing futile, unsuccessful and grossly negligent treatment

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 28 of 87 PageID #: 28 at the hands of the defendants, and impaired quality of life.

- 104. The defendants worked to attract as many patients as possible from Italy to the International Patient Program without adequate planning or coordination to properly evaluate, treat, and monitor these patients.
- 105. The defendants undertook and rendered futile, unnecessary, and negligent treatment to dozens of Italian nationals, including the plaintiffs herein, for many forms of cancer between 2001 and 2003.
- 106. The plaintiffs' arrival at the defendants' facilities was barely acknowledged by the defendants for days at a time.
- 107. When the patients, including the plaintiffs herein, arrived at the defendants' facilities in .

 New York, their needs were ignored, they received inadequate treatment, and adequate translation services were not provided at all times necessary.
- 108. Many patients, including the plaintiffs herein, waited several days before they were seen by any hospital personnel or by the defendant doctors.
- 109. After days of frustration, many patients and their families, including the plaintiffs herein, vented their frustrations to the defendants.
 - 110. The defendants responded to the deteriorating situation by threatening to return patients to

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 29 of 87 PageID #: 29 Italy without treating them and using security guards to silence concerned family members who were allegedly "making too much noise" about the lack of treatment and information.

- 111. The defendants administered the futile, unproductive, and ineffectual Fractionated Stereotactic Radiosurgery treatment to the plaintiffs.
- 112. The defendants failed to adequately evaluate and diagnose the patients, including the plaintiffs herein, before administering the Fractionated Stereotactic Radiosurgery treatment.
 - 113. The defendants were negligent in the care and treatment rendered to the plaintiffs.
- 114. Defendants failed to perform their own pathology studies on patients, including the plaintiffs herein, before administering treatment.
- 115. On several occasions, defendants refused to wait for plaintiffs' pathology to clear customs before administering the treatments, and thereafter failed to conduct their own tests to confirm the condition of the patients they were about to treat.
- 116. Upon information and belief, on at least two occasions, the defendants accepted and treated patients who did not have cancer, including the deceased plaintiff BONO.
- 117. The defendants violated applicable statutes, rules, regulations and/or protocol by administering stereotactic radiosurgery to patients, including the plaintiffs herein, without confirming that the patients had cancer, all of which deviates from accepted standards of care.

- 118. The defendants treated patients, including the plaintiffs herein, when there was no reasonable benefit to be derived, and/or no reasonable expectation that their quality of life would be improved, or extended.
- 119. The defendants treated patients, including the plaintiffs herein, when there was no hope for survival or for extending their life expectancy.
- 120. The defendants treated patients, including the plaintiffs herein, in a negligent manner, deviating from accepted standards of care.
- 121. The defendants, after luring patients to their visiting patient program, including the plaintiffs herein, failed to fulfill their promises for accommodating patients and their families during their stay and providing proper treatment and care to the patients.
- 122. The defendants failed to obtain informed consent from the patients, including the plaintiffs herein, in that they failed to provide plaintiffs with the benefits, risks, and alternatives regarding the proposed treatments, and/or provided misleading information regarding the benefits, risks, and alternatives.
- 123. The defendants systematically and repeatedly denied patients, including the plaintiffs herein, access to and copies of their medical records, test results, films, or any documentation or information.
 - 124. Even though defendants told patients, including the plaintiffs herein, that they needed to

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 31 of 87 PageID #: 31 follow-up with their doctors in Italy two to three months after their return, the defendants mexplicably ignored patients' requests, and the requests of their Italian oncologists, for their treatment records in defendants' possession.

- 125. The patients, including the plaintiffs herein, repeatedly made desperate pleas for their medical records to the defendants as their conditions rapidly deteriorated during their stay at defendants' facilities and/or upon returning to Italy, but these pleas were inexplicably ignored by the defendants.
- 126. Defendants' administration of treatment to the patients, including the plaintiffs herein, was grossly negligent, careless, futile, and unnecessary.
- 127. Defendants knew that their administration of treatment to the patients, including the plaintiffs herein, was grossly negligent, careless, futile, and unnecessary.
- 128. The patients, including the plaintiffs herein, suffered increased fatigue, weakness, nausea, vomiting, and pain, and their condition deteriorated, with increasing frequency after each administration.
- The defendant doctors on occasions too numerous to specify, in response to patient complaints of pain, including the plaintiffs herein, responded falsely by telling the patients that they were "doing very well ... recovering well ... that (their) increasing pain was normal and merely demonstrated that the cancer cells were dying ...," or that they were "merely depressed."
- 130. The patients, including the plaintiffs herein, contrary to the promises made by the defendants, personally and through various advertising media, did not benefit from stereotactic

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 32 of 87 PageID #: 32 radiosurgery. Indeed, the plaintiffs' deaths were hastened by the treatment, rather than enjoying a greater life expectancy, and the condition of those still living deteriorated significantly.

- 131. The defendants' actions and conduct deprived the patients, including the plaintiffs herein, from obtaining and/or continuing with necessary and appropriate care and treatment in Italy.
- 132. The majority of the patients treated, including the deceased plaintiffs, died shortly after treatment.

■ RACKETEER INFLUENCED & CORRUPT ORGANIZATIONS ACT ■ RICO ■

- 133. The defendant hospitals breached their duty to use reasonable care in hiring, training, and supervising their employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators of the defendants, including members of its medical staff, and in violating state regulations, and in conspiring to violate New York State consumer protection and public health laws, and, indeed, New York State's Penal Law, by falsely and fraudulently representing to the plaintiffs and other terminally ill cancer patients through aggressive, false advertising and fraudulent self-promotion that the defendants could cure and/or control their cancers.
- 134. During the period of time from 2001 to 2003 the defendants made the aforementioned oral and written misrepresentations of material facts, and also concealed material facts from the plaintiffs and the public at large, including the non-disclosure to the plaintiffs:
 - (a) that in 1999 the New York State Attorney General secured an agreement from the defendant SIUH to pay \$45 million (plus an additional \$39 million dollars in free services to indigent patients) to settle a Medicaid fraud case which included among the fraudulent acts the overbilling of SIUH patients;

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- (b) that since 1996 the Office of the Inspector General of the United States Department of Health and Human Services had been investigating the defendant SIUH for misrepresentations in overstating the number of residents on staff studying at SIUH, thereby resulting in an overfunding by the federal government of the hospital's graduate medical education program;
- (c) that in 2000 the defendants GROSSMAN, LEDERMAN, and SIUH were sued for malpractice for unnecessarily administering Fractionated Stereotactic Radiosurgery to a patient (in 2004 the jury awarded \$5.5 million for the unnecessary radiosurgery); and
- (d) that in November 2003 the defendant LEDERMAN entered into an agreement with the New York State Department of Health, which had investigated allegations of professional misconduct in connection with the defendant's treatment of George Harrison, the Beatle, for releasing information about Mr. Harrison, without Mr. Harrison's consent, resulting in a censure and a \$5,000.00 fine to the defendant LEDERMAN (notwithstanding the defendants' earlier express and implicit oral representations to the plaintiffs that the defendants' Fractionated Stereotactic Radiosurgery had been chosen by Mr. Harrison, a world famous entertainer, who could afford any treatment, any where, any time).
- 135. The defendants' material misrepresentations and concealment of material facts were made intentionally and/or with a reckless disregard for the truth, to carry out a common scheme, artifice and fraud to unjustly enrich the defendants, at a cost to the plaintiffs of their health and very lives.
- 136. The plaintiffs reasonably and justifiably relied to their detriment on that which they believed to be the truthfulness of the defendants' representations and the defendants' full disclosure of material facts, and each plaintiff thereby was induced to pay \$17,500.00 (exclusive of round trip traveling costs and expenses to and from Italy and New York) to the defendants for the advertised living accommodations in, and Fractionated Stereotactic Radiosurgery treatment at the defendants' hospitals in Staten Island.
- 137. The defendant's enterprise was, and continues to be, engaged in interstate and foreign commerce, to wit, the delivery of medical, hospital and healthcare services to the citizens of other states

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 34 of 87 PageID #: 34 and foreign countries.

- 138. During the period of time from 2001 to 2003 the defendants conspired to engage in a pattern of racketeering activity, and actually engaged in that pattern of racketeering activity on between 100 and 200 occasions by making the aforementioned intentional, fraudulent representations by use of the wires (including the Internet, and telephone) and the mails, and by concealing material facts, and by engaging in false advertising practices in order to defraud the plaintiffs and the public at large to induce them to purchase the defendants' Fractionated Stereotactic Radiosurgery treatment.
- 139. The fraudulently induced purchase of the Fractionated Stereotactic Radiosurgery treatment actually caused the plaintiffs to sustain injuries and damages apart from the cost paid to the defendants, including bodily and psychological injuries; loss of the opportunity to receive appropriate treatment in Italy or elsewhere to increase the probability of length of survival with a greater quality of life; loss of the opportunity to receive systematic palliative care in Italy or elsewhere; pain and suffering; wrongful death; and loss of consortium.
- 140. The defendants, in furtherance of their scheme to defraud the plaintiffs and the public at large to carry out their pattern of racketeering activity, violated federal and state criminal laws, including false advertising, mail fraud, wire fraud, engaging in the unauthorized practice of medicine, engaging in the unauthorized use of a professional title, and aiding and abetting the defendant SALVATORE CONTE to engage in the unauthorized practice of medicine.

Violation of New York State General Business Law §349 and 350

- 141. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 142. During the period from 2001 to 2003, the defendants engaged in deceptive acts and practices in furnishing, and in falsely advertising, Fractionated Stereotactic Radiosurgery treatment to the plaintiffs and the public at large, by making the following false claims, *inter alia*, in their print advertisements and in radio and television commercials, and on the Internet:

The defendants made the following misleading, fraudulent, deceitful, and shocking claims, statements, and information in their "Fractionated Stereotactic Body Radiosurgery" marketing booklet:

"Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery - 90 percent - are successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."

"The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area - meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."

"Many patients were so-called 'hopeless cases' before coming to Staten Island University Hospital."

The booklet then continues with the following outrageous, misleading and false representations:

"Primary Liver Cancers: ... In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90 percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."

"Liver Metastases: ... We have a success rate of 88 percent ..."

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 36 of 87 PageID #: 36 "Primary Lung Carcinomas: ... The local control rate is 89 percent."

"Pulmonary or Lung Metastases: ... The local control rate is 88 percent. Many patients come to us with severe lung disease not felt to be candidates for standard surgery or radiation."

"Primary Pancreas Cancers: Primary pancreas cancers have been treated with a very high rate of success. In fact, 94 percent of primary pancreas cancers currently have been successfully controlled in the treated area with Body Radiosurgery at Staten Island University Hospital. Many included patients who had extensive prior unsuccessful treatment ... Furthermore, the size of the cancers treated with Body Radiosurgery here was, on average, three times the size and still we had a dramatically higher success rate. Thus, our success rate locally for pancreas cancers is 94 percent."

"Other Abdominal Tumors: ... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as adrenal glands and pre-sacral metastases. The local control rate for adrenal tumors is 94 percent."

The plaintiffs also relied on the misinformation and fraudulent claims disseminated by the defendants, described in detail in Paragraph 41, *supra*.

143. One of the videotapes, "Fractionated Stereotactic Body Radiosurgery," included the following false, fraudulent, misleading, and shocking claims, statements, and information by defendant LEDERMAN:

"... 90% success rate. Success means cessation of growth, shrinkage, or disappearance of the cancer. It's quick—each treatment takes thirty minutes or less and patients can go home and back to their normal activities very quickly after treatment. Many people call it a treat, not a treatment because of the effectiveness and the lack of toxicity in general."

Defendants created and disseminated a videotape entitled "The Radiosurgery Center, Fractionated Stereotactic," which included the following false, fraudulent, misleading, and shocking claims, statements, and information:

"This new treatment is non-invasive, highly successful, and offers great hope to those who previously thought there was none."

"Tremendous results, results in many hopeless cases, people who thought there were no chances for them are coming, and many, many are

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 37 of 87 PageID #: 37 having chances, another break at life."

"Tremendous results," "very high success rate," and a "90% success rate" are repeatedly touted claims.

- 144. Defendants held out defendant SALVATORE CONTE as a medical doctor and oncologist at the conferences.
- 145. In fact, certain of defendants' televised broadcasts contained a subscript at numerous times while defendant SALVATORE CONTE is speaking, identifying him as a medical doctor and an oncologist.
- 146. Defendants provided defendant SALVATORE CONTE with business cards identifying him as a medical doctor and oncologist.
 - 147. That defendant SALVATORE CONTE was not a medical doctor, let alone an oncologist.
- 148. The fraudulently induced purchase of the Fractionated Stereotactic Radiosurgery treatment actually caused the plaintiffs to sustain injuries and damages apart from the cost paid to the defendants, including bodily and psychological injuries; loss of the opportunity to receive appropriate treatment in Italy or elsewhere increasing the probability of length of survival with a greater quality of life; loss of the opportunity to receive systematic palliative care in Italy or elsewhere; pain and suffering; wrongful death; and loss of consortium.
- 149. By reason of the foregoing each plaintiff suffered compensatory damages of no less than of no less than \$10,000,000.00 together with treble damages and an award of counsel fees and costs and disbursements.

Common Law Fraud

- 150. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 151. During the period from 2002 to 2003 the defendants made the following intentional, fraudulent representations, with the intention of deceiving the plaintiffs and the public at large, knowing that the plaintiffs would rely thereon and thereby be induced to submit to and pay for Fractionated Stereotactic Radiosurgery treatment at the defendants' hospital in Staten Island: The defendants, in their marketing kit, defined Fractionated Stereotactic Radiosurgery as "... precision radiation using multiple, finely contoured beams from many different angles all directed at the cancer, minimizing radiation to normal healthy tissue. A non-invasive stereotactic frame maintains the body in a stable, reproducible position. A stereotactic body frame secures this position which is painlessly and non-invasively custom-molded about the body."
- 152. The plaintiffs did reasonably rely on the defendants intentional misrepresentations, and were damaged thereby in being lured and enticed by false, fraudulent and deceitful advertisements and misrepresentations, including representations that the radiosurgery treatment had "tremendous results" with extraordinary and enticingly high success rates for various forms of cancer.
- 153. The defendants made the following misleading, fraudulent, deceitful, and shocking claims, statements, and information in their "Fractionated Stereotactic Body Radiosurgery" marketing booklet:

"Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery - 90 percent - are successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 39 of 87 PageID #: 39 for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."

"The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area - meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."

"Many patients were so-called 'hopeless cases' before coming to Staten Island University Hospital."

The booklet then continues with the following outrageous, misleading and false representations:

"Primary Liver Cancers: ... In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90 percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."

"Liver Metastases: ... We have a success rate of 88 percent ..."

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"Other Abdominal Tumors: ... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as adrenal glands and pre-sacral metastases. The local control rate for adrenal tumors is 94 percent."

The plaintiffs also relied on the misinformation and fraudulent claims disseminated by the defendants, described in detail in Paragraph 41, *supra*.

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 40 of 87 PageID #: 40 154. One of the videotapes, "Fractionated Stereotactic Body Radiosurgery," included the

following false, fraudulent, misleading, and shocking claims, statements, and information by defendant

LEDERMAN:

"... 90% success rate. Success means cessation of growth, shrinkage, or disappearance of the cancer. It's quick—each treatment takes thirty minutes or less and patients can go home and back to their normal activities very quickly after treatment. Many people call it a treat, not a treatment because of the effectiveness and the lack of toxicity in general."

Defendants created and disseminated a videotape entitled "The Radiosurgery Center, Fractionated Stereotactic," which included the following false, fraudulent, misleading, and shocking claims, statements, and information:

"This new treatment is non-invasive, highly successful, and offers great hope to those who previously thought there was none."

"Tremendous results, results in many hopeless cases, people who thought there were no chances for them are coming, and many, many are having chances, another break at life."

"Tremendous results," "very high success rate," and a "90% success rate" are repeatedly touted claims.

- 155. Defendants held out defendant SALVATORE CONTE as a medical doctor and oncologist at the conferences.
- 156. In fact, certain of defendants' televised broadcasts contained a subscript at numerous times while defendant SALVATORE CONTE is speaking, identifying him as a medical doctor and an oncologist.
- 157. Defendants provided defendant SALVATORE CONTE with business cards identifying him as a medical doctor and oncologist.

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- 158. The systematic dissemination of misinformation and promotion of false hope were designed to lure vulnerable cancer patients, including the plaintiffs herein, and their loved ones, to the defendants' stereotactic radiosurgery program in New York.
- 159. The plaintiffs reasonably relied on the false, misleading and deceitful information to undergo the promoted Fractionated Stereotactic Radiosurgery treatment
 - 160. The plaintiffs herein were in fact deceived and misled by the defendants.
- 161. Based upon the plaintiffs' reasonable reliance on the defendants' material misrepresentations, the plaintiffs were entited to leave Italy and undergo treatment by the defendants in Staten Island, but the majority of the patients treated, including the deceased plaintiffs, died shortly after treatment, sometimes within weeks, sometimes within months.
- 162. The fraudulently induced purchase of the Fractionated Stereotactic Radiosurgery treatment actually caused the plaintiffs to sustain injuries and damages apart from the cost paid to the defendants, including bodily and psychological injuries; loss of the opportunity to receive appropriate treatment in Italy or elsewhere increasing the probability of length of survival with a greater quality of life; loss of the opportunity to receive systematic palliative care in Italy or elsewhere; pain and suffering; wrongful death; and loss of consortium.
- 163. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

Unjust Enrichment

164. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with

the same force and effect as if set forth at length herein.

165. Defendants charged each patient, including the plaintiffs herein, \$17,500.00 to enter the

program, which said fee had to be paid in advance, and which did not include the plaintiffs' traveling

expenses to and from Staten Island and Italy.

166. The defendants included with the aforementioned "acceptance letter" to the patients,

including the plaintiffs herein, instruction sheets for payment, travel arrangements, and miscellaneous

logistical information regarding the defendants' facilities in New York, which included a 10% payment

(\$1,750.00) to be made directly to defendant SALVATORE CONTE's personal banking account by wire

transfer.

167. The defendants negotiated this kickback with defendant SALVATORE CONTE as well as

payment of his overhead expenses and office space in Naples, Italy, in consideration for his promise to meet

defendants' quota for patients.

168. The kickback arrangement was discussed and approved at several meetings at the

defendants' facilities in New York and/or in Italy among defendants consisting of at least LEDERMAN,

SILVERMAN, GROSMAN, JOSEPH CONTE, SALVATORE CONTE, GELMI-NOURBAHA, and

perhaps others.

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- 169. The instructions also directed the patients, including the plaintiffs herein, to wire the balance of the charges to the defendant SIUH's operating account in New York.
- 170. The patients, including the plaintiffs herein, did in fact wire the balance of the charges to the defendant SIUH's operating account in New York.
- 171. In consideration of his efforts, the defendants also paid defendant LEDERMAN a set percentage of the monies received from the plaintiffs for their treatment, to wit, 20% (\$3,500.00) of the overall fee.
- 172. In some instances, the patients, including the plaintiffs herein, received instructions to wire a portion of the funds directly into defendant LEDERMAN's account in New York.
- 173. In some instances, the patients, including the plaintiffs herein, did in fact wire a separate sum into defendant LEDERMAN's account in New York.
- 174. Only upon full payment of the requisite fees could the patients, including the plaintiffs herein, be processed and scheduled for treatment.
- 175. The hospital defendants, upon information and belief, received gross annual fees between \$5,000,000.00 and \$10,000,000.00 during the period beginning in 2001 for radio therapy, including stereotactic body radiosurgery, and thereby were unjustly enriched.
 - 176. By reason of the foregoing each plaintiff suffered compensatory damages of no less than

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 44 of 87 PageID #: 44 \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

COUNT IV

Hospital and Medical Negligence

- 177. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 178. The defendants were negligent, careless and reckless in their failure to provide proper medical care, treatment, diagnoses and assistance to the defendants.
- 179. As a direct cause of the defendant's gross, wilful, wanton negligence, the plaintiffs suffered severe injuries, including pain; loss of the opportunity to obtain treatment which had a probability of prolonging their lives, loss of the opportunity to obtain systematic palliative care; loss of the opportunity to receive necessary and appropriate care; undergoing unnecessary, inappropriate and unsuccessful treatment which caused pain and suffering; psychological damages; aggravation and exacerbation of cancer related pain and suffereing, fatigue, weakness, loss of appetite, dehydration; bowel problems; physical and psychological deterioration; aggravation and exacerbation of fatigue, weakness, loss of appetite; aggravation and exacerbation of depression; decreased quality of life; decreased length of life.
- 180. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed, neglected, and/or intentionally refused to use reasonable care in the employment, training, supervision, and the retention of those defendants engaging in the marketing, selling, and administering of Fractionated

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 45 of 87 PageID #: 45 Stereotactic Radiosurgery, in order to determine whether those defendants were competent to do their work and perform the treatments without danger of harm to others, in this case, the plaintiffs.

- 181. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed, neglected, and/or intentionally refused to conduct an investigation of the efficacy of administering of Fractionated Stereotactic Radiosurgery when the many deaths of patients soon after treatment, including the plaintiffs, would lead a reasonably prudent person to conclude that the treatment was contraindicated and should have been terminated.
- 182. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed and/or neglected to act prudently, their errors of commission and omission negligently resulted in scrious personal injuries and death to the plaintiffs.
- 183. The defendants were motivated by greed and bottom line profit objectives, and their intentional refusal to terminate timely the administration of Fractionated Stereotactic Radiosurgery resulted in serious personal injuries and death to the plaintiffs.
- 184. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

Negligent Misrepresentation

- 185. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 186. The defendants were careless, reckless, and otherwise grossly and wantonly negligent in failing to take reasonable care by not conducting a simple review to determine whether the representations made in their marketing media devices were accurate, knowing full well that the claims were made for the benefit and purpose of inducing other persons, including the plaintiffs, to rely thereon.
- 187. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

COUNT VI

Breach of Warranty

- 188. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 189. The defendants, retained by the plaintiffs in reliance on the defendants' representations for the predominant purpose of rendering services, to wit, Fractionated Stereotactic Radiosurgery, breached their express and/or implied warranties to cure or control cancer, thereby making the defendants strictly

- 190. The defendants SIUH, NORTH SHORE-LIJ, and NORTH SHORE-LIJ SYSTEM, failed, neglected, and/or intentionally refused to use reasonable care in the employment, training, supervision, and the retention of those defendants engaging in the marketing, selling, and administering of Fractionated Stereotactic Radiosurgery, in order to determine whether those defendants were competent to do their work and perform the treatments without danger of harm to others, in this case, the plaintiffs.
- 191. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

COUNT VII

Medical Malpractice

- 192. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 193. That at all times herein mentioned, the defendant LEDERMAN, was and still is a physician duly licensed to practice medicine in the State of New York, and the defendant GILBERT LEDERMAN, M.D., P.C. was and still is a professional corporation owned solely by the defendant LEDERMAN.
- 194. That at all times herein mentioned, defendant SILVERMAN was and still is a physician duly licensed to practice medicine in the state of New York.

- 195. That at all times herein mentioned, defendant GROSMAN was and still is a physician duly licensed to practice medicine in the state of New York.
- 196. That at all times herein mentioned, defendant LEDERMAN claimed to be a specialist in oncology.
- 197. That at all times herein mentioned, defendant SILVERMAN claimed to be a specialist in oncology.
- 198. That at all times herein mentioned, defendant GROSMAN claimed to be a specialist in oncology.
- 199. That at all times herein mentioned, defendant SALVATORE CONTE falsely represented himself to be a medical doctor, and the defendants encouraged, aided, and abetted defendant SALVATORE CONTE in his unauthorized practice of medicine and in holding the defendant SALVATORE CONTE out as a medical doctor, and in encouraging him to use the unauthorized title.
- 200. That at all the times herein mentioned, defendant LEDERMAN including his professional corporation was a member of the medical staff of the defendants' hospital.
- 201. That at all the times herein mentioned, defendant SILVERMAN was a member of the medical staff of the defendants' hospital.

- 202. That at all the times herein mentioned, defendant GROSMAN was a member of the medical staff of the defendants' hospital.
- 203. That at all the times herein mentioned, defendant LEDERMAN, including his professional corporation, was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendant hospitals.
- 204. That at all the times herein mentioned, defendant SILVERMAN was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendant hospitals.
- 205. That at all the times herein mentioned, defendant GROSMAN was an employee, servant, agent, representative partner and/or joint venturer and/or co-conspirator of the defendant hospitals.
- 206. That at all the times herein mentioned, defendant LEDERMAN attended said patients, including the plaintiffs herein, in the course of his business dealings with the defendants' hospital.
- 207. That at all the times herein mentioned, defendant SILVERMAN attended said patients, including the plaintiffs herein, in the course of his business dealings with the defendants' hospital.
- 208. That at all the times herein mentioned, defendant GROSMAN attended said patients, including the plaintiffs herein, in the course of her business dealings with the defendants' hospital.
- 209. That at all the times herein mentioned, defendant LEDERMAN (including his professional corporation) rendered medical services to patients, including the plaintiffs herein, at the facility of the

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 50 of 87 PageID #: 50 defendants' hospital, pursuant to an agreement with said hospitals.

- 210. That at all the times herein mentioned, defendant SILVERMAN rendered medical services to patients, including the plaintiffs herein, at the facility of the defendants' hospital, pursuant to an agreement with said hospital.
- 211. That at all the times berein mentioned, defendant GROSMAN rendered medical services to patients, including the plaintiffs herein, at the facility of the defendants' hospital, pursuant to an agreement with said hospital.
- 212. That between May 2002 and 2003, the plaintiffs were under the care of the defendant hospitals and the aforesaid defendant doctors, including the defendant SALVATORE CONTE, who was falsely represented to the plaintiffs to be a medical doctor and a specialist in oncology.
- 213. That between May 2002 and 2003, the plaintiffs engaged the defendants LEDERMAN, SILVERMAN, GROSMAN, and SALVATORE CONTE, and their agents, servants, and employees, as physicians to diagnose, treat and cure a condition from which plaintiffs were then suffering, and that said defendants undertook as such physicians to attend and care for such plaintiffs and to use due reasonable and proper skill and care in their treatment.
- 214. That between May 2002 and 2003, the plaintiffs engaged the defendant hospitals, it's employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators, to diagnose, treat and cure a condition from which plaintiffs were then suffering, and that said plaintiffs undertook said hospitals to attend and care for such patients, and to use due reasonable and proper skill and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 51 of 87 PageID #: 51 care in the treatment of the patients.

- 215. That defendants LEDERMAN, SILVERMAN, and GROSMAN, and their agents, servants, and employees, did not use due, reasonable or proper skill or care in efforts to cure said patients, including the plaintiffs herein, of such condition, but, instead, negligently and carelessly failed to discover plaintiffs' true conditions; incorrectly and/or improperly diagnosed the said conditions and undertook to treat plaintiffs therefor; and failed to exercise the knowledge, skill and diligence which a physician should have possessed and exercised on the plaintiffs' behalf; and as a result of such failure to diagnose the said conditions properly and to treat plaintiffs therefor, plaintiffs sustained the injuries and damages herein alleged, and the deceased plaintiffs were caused to expire.
- 216. That defendant hospitals, their employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators, did not use due, reasonable or proper skill or care in efforts to cure said patients, including the plaintiffs herein, of such condition but, instead, negligently and carelessly failed to discover plaintiffs' true conditions; incorrectly and improperly diagnosed the said condition and undertook to treat plaintiffs therefor; and failed to exercise the knowledge, skill and diligence which they should have possessed and exercised on the plaintiffs' behalf; and as a result of such failure to diagnose the said condition properly and to treat plaintiffs therefor, plaintiffs sustained the injuries and damages herein alleged, and the deceased plaintiffs were caused to expire.
- 217. That the negligence of the defendants LEDERMAN, SILVERMAN, and GROSMAN and their agents, servants, and employees, consisted of, *inter alia*, negligently, recklessly and carelessly violating the custom and practice in the community in treating the said patients, including the plaintiffs herein; in negligently, recklessly and carclessly failing to properly diagnose and discover the plaintiffs' true

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 52 of 87 PageID #: 52 conditions; in negligently, recklessly and carelessly failing to take appropriate tests and x-rays and perform other procedures to determine the true nature of the underlying conditions; in negligently, recklessly and carelessly failing to remove the source of the plaintiffs' complaints; in casually and in a manner inconsistent with good medical practice undertaking the care of the said plaintiffs; and in failing and neglecting to caution or to warn the plaintiffs of the potential dangers which, in the exercise of due care, should have been apparent to a competent physician.

- 218. That the negligence of the defendant hospitals consisted of, *inter alia*, negligently, recklessly and carelessly violating the custom and practice in the community in treating the said patients, including the plaintiffs' herein; in negligently, recklessly and carelessly failing to properly diagnose and discover the plaintiffs' true conditions; in negligently, recklessly and carelessly failing to take appropriate tests and x-rays and perform other procedures to determine the true nature of the underlying conditions; in negligently, recklessly and carelessly failing to remove the source of the plaintiffs' complaints; in casually and in a manner inconsistent with good medical practice undertaking the care of the said plaintiffs; and in failing and neglecting to caution or to warn the plaintiffs of the potential dangers which, in the exercise of due care, should have been apparent to a competent physician serving as the defendant hospitals' employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators.
- 219. That the defendants failed to obtain informed consent from the patients, including the plaintiffs herein, in that they failed to provide plaintiffs with the benefits, risks, and alternatives regarding the proposed treatments, and/or providing misleading information regarding the benefits, risks, and alternatives.
 - 220. That between May 2002 and 2003, the plaintiffs were treated by the defendant doctors and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 53 of 87 PageID #: 53 **hospitals.**

- 221. That during the confinement of the plaintiffs, the defendant-physicians were under the direction, control and supervision of the various governing boards, committees and appropriate departmental chairpersons of the defendant hospitals including the defendant hospitals' trustees and officers.
- 222. That at the aforesaid times and places, the defendant physicians should have been required by the defendant hospitals, their employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators, to perform all professional duties, activities and responsibilities in accordance with the by-laws, rules and regulations which should have been established by the defendant hospitals for the regulation and supervision of physicians rendering care.
- 223. That during the plaintiffs' confinement to the defendant hospital, the defendant physicians were under the direction, control and supervision of the various governing boards, committees and appropriate departmental chairpersons of the defendant hospital.
- 224. That as a result of the foregoing, plaintiff GIUSEPPA CARAMANNA BONO sustained severe physical injuries resulting in her death.
- 225. That as a result of the foregoing, plaintiff DINO BROVELLI sustained severe physical injuries resulting in his death.
 - 226. That as a result of the foregoing, plaintiff DINO CATTAI sustained severe physical injuries

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 54 of 87 PageID #: 54 resulting in his death.

- 227. That as a result of the foregoing, plaintiff FRANCESCO CENTORE sustained severe physical injuries resulting in his death.
- 228. That as a result of the foregoing, plaintiff GIUSEPPE DiGANCI sustained severe physical injuries resulting in his death.
- 229. That as a result of the foregoing, plaintiff ROBERTO ETTORE sustained severe physical injuries resulting in his death.
- 230. That as a result of the foregoing, plaintiff MASSIMO FACCHINI sustained severe physical injuries resulting in his death.
- 231. That as a result of the foregoing, plaintiff GIANCARLA PESCI sustained severe physical injuries resulting in a marked deterioration in her health and the necessity for continued treatment in Italy.
- 232. That as a result of the foregoing, plaintiff, ANTONIO RODA sustained severe physical injuries resulting in a marked deterioration in his health and the necessity for continued treatment in Italy.
- 233. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

Violation of New York State Public Health Law §2805-d

- 234. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 235. The defendants failed, neglected, and/or intentionally refused to disclose to plaintiffs the reasonably foreseeable benefits, risks and alternatives, including the probabilities of occurrence to the treatment they provided, including Fractionated Stereotactic Radiosurgery to the pancreas, Fractionated Stereotactic Radiosurgery to the liver and whole liver radiation.
- 236. The defendants failed, neglected, and/or intentionally refused to disclose to plaintiffs the reasonable benefits, risks and alternatives to their treatment, and their probability of occurrence, as a reasonable physician under the circumstances would have disclosed, in a manner permitting plaintiff decedents to make and informed choice and knowledgeable evaluation of their treatment options, and whether to consent to the treatment offered by the defendants.
- 237. The defendants failed, neglected, and/or intentionally refused to disclose that the Fractionated Stereotactic Radiosurgery treatment for pancreatic cancer was not the standard of care in the fields of oncology and medicine for pancreatic cancer and was merely experimental and not in conformity with generally accepted principles in oncology, medicine and science.
- 238. The defendants failed, neglected, and/or refused to disclose that the Fractionated Stereotactic Radiosurgery treatment for liver metastases was not the standard of care in the fields of oncology and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 56 of 87 PageID #: 56 medicine for liver metastases and was merely experimental and not in conformity with generally accepted principles in oncology, medicine and science.

- 239. The defendants failed, neglected, and/or intentionally refused to disclose that the Fractionated Stereotactic Radiosurgery treatment for pancreatic cancer with liver metastases was not the standard of care in the fields of oncology and medicine for pancreatic cancer with liver metastases and was merely experimental and not in conformity with generally accepted principles in oncology, medicine and science.
- 240. Neither plaintiffs nor a reasonably prudent person in plaintiffs' position would have undergone the treatment, including Fractionated Stereotactic Radiosurgery to the pancreas, Fractionated Stereotactic Radiosurgery to the liver and whole liver radiation if plaintiffs had been fully informed by defendants.
- 241. Since plaintiffs relied upon the aforementioned false, misleading and deceptive representations disseminated by defendants to plaintiffs and their families regarding the nature, benefits, risks and alternatives to the treatment at SIUH, plaintiffs could not and did not make an informed consent to the treatment provided by defendants.
- 242. The lack of informed consent is a proximate cause of the injuries and damages sustained by plaintiffs, including severe pain and suffering; loss of opportunity to obtain treatment which had a probability of prolonging their lives; loss of opportunity to obtain systematic palliative care; loss of the opportunity to receive necessary and appropriate care; undergoing unnecessary and unsuccessful treatment which caused pain and suffering; aggravation and exacerbation of cancer related pain and suffering; fatigue,

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 57 of 87 PageID #: 57 weakness, loss of appetite, dehydration; aggravation and exacerbation of depression; decreased quality of life; loss of the opportunity to prolong their lives and have a better quality of life in the time remaining plaintiffs; loss of the right to make an informed decision as to what treatments, if any, plaintiffs should undergo.

243. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

COUNT IX

Wrongful Death

- 244. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 245. By virtue of the wrongful deaths of the deceased plaintiffs, the heirs and distributees of the decedents, GIUSEPPA CARAMANNA BONO, DINO BROVELLI, DINO CATTAI, FRANCESCO CENTORE, GIUSEPPE DiGANCI, ROBERTO ETTORE, and MASSIMO FACCHINI, have been deprived of the support, maintenance, and society of the prior relationship and communion with the decedents, as well as of the decedents' society, guidance and of potential enhanced inheritance from said decedents.
- 246. That in connection with the injuries suffered by the deceased plaintiffs, and the resulting deaths, plaintiffs necessarily incurred, and have become obligated to pay funeral and other additional

- 247. As a result of the foregoing, the distributees and next of kin of the said decedents have sustained damages; that as a result of the aforesaid occurrence, plaintiffs' decedents sustained severe injuries to their bodies and limbs, a severe shock to the nervous system and certain internal injuries, and were caused to suffer severe pain and mental anguish which said injuries resulted in death, with resulting expenses or obligation for funeral and burial, all to the damage of the said decedents and plaintiffs herein.
- 248. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

COUNT X

Loss of Consortium

- 249. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 250. The surviving spouses of the deceased plaintiffs, GIUSEPPE BONO for GIUSEPPA CARAMANNA BONO, PATRIZIA SIRAGUSA BROVELLI for DINO BROVELLI, VIRGINIA GRANDIN CATTAI for DINO CATTAI, MARIA MENSITIERI CENTORE for FRANCESCO CENTORE, MARIA RITA PULEO DIGANCI for GIUSEPPE DIGANCI, CARMELA FRAMMARTINO ETTORE for ROBERTO ETTORE and FEDERICA LOSACCO FACCHINI for MASSIMO FACCHINI, respectively, sustained the loss of services, society, companionship and consortium of their spouses and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 59 of 87 PageID #: 59 were forced to spend money for their care and treatment, all as a result of the defendants' gross negligence and wilful misconduct.

251. By reason of the foregoing each of the deceased plaintiffs' spouses suffered compensatory damages of no less than \$2,000,000.00.

COUNT XI

Violation of Lanham Act 15 U.S.C. §1125

- 252. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 253. The defendants' fraudulent representations of material facts, their omission by concealment of material facts, and their false commercial advertising and promotions misrepresenting the Fractionated Stereotactic Radiosurgery treatment was likely to, and did, cause the plaintiffs and the public at large to approve and subsequently pay good and valuable consideration for the Fractionated Stereotactic Radiosurgery medical services.
- 254. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

RICO Violation, 18 U.S.C. §1961 et seg.

- 255. The plaintiffs repeat and reallege all allegations contained in the preceding paragraphs with the same force and effect as if set forth at length herein.
- 256. Each of the corporate and individual defendants is a "person" capable of holding a legal or beneficial interest in property as required by 18 U.S.C.A §1961(3).
- 257. The corporate and individual defendants, and the defendants associated in fact, even if not a legal entity (i.e., SIUH, NORTH SHORE-LIJ, NORTH SHORE-LIJ SYSTEM), constitute the "enterprise" required by 18 U.S.C.A. §1961(4).
- 258. The defendants engaged in a "pattern of racketeering activity" required by 18 U.S.C.A. §1961(5), hereinabove and hereinafter described, during the period from 2001 to 2003 consisting of the commission of various misdemeanors under New York State Penal Law §190.20, New York State Education Law §6513(1), an E felony under New York State Education Law §6512, and between 100 and 200 instances of mail and wire fraud under 18 U.S.C.A §§1341 and 1343.
- 259. The pattern of racketeering activity engaged in on behalf of the defendants' enterprise affected interstate or foreign commerce, and was unlawful under 18 U.S.C.A. §1962(b) and/or (c).
- 260. The plaintiffs' injuries and deaths were proximately caused by the pattern of racketeering activity hereinabove and hereinafter alleged, to wit, the commission of at least twenty-four mail and wire

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 61 of 87 PageID #: 61 frauds committed against the instant plaintiffs, as follows: the defendants' false advertising and misrepresentations of material facts were made, initially, via the Internet from the United States to Italy (followed by television commercials, and, in some cases, group meetings with the defendants LEDERMAN, SALVATORE CONTE and GELMI-NOURBAHA), including instructions to call the defendant SALVATORE CONTE (who was misrepresented to be a medical doctor specializing in oncology), who, after allegedly examining CT scans and other imaging, had the defendant GELMI-NOURBAHA telephone the plaintiffs from the United States to Italy, giving instructions in the Italian language for travel and living accommodations at the hospital site of the defendant SIUH, all of which was followed by a letter of acceptance from the defendants, posted in the United States, and mailed to the plaintiffs in Italy.

- 261. The defendants engaged in a scheme or artifice to defraud the plaintiffs and the public at large by intentionally and deliberately engaging in false advertising and asserting false and fraudulent representations and asserting half truths known to be misleading, with the expectation that the public at large and the plaintiffs in particular would rely thereon to the benefit of the defendants and the detriment of the plaintiffs.
- 262. The defendants engaged in a scheme or artifice to defraud the plaintiffs and the public at large by intentionally and deliberately engaging in a suppression of material facts, with the expectation that the public at large and the plaintiffs in particular would not have sought Fractionated Stereotactic Radiosurgery treatment had the material facts been disclosed.
- 263. The defendants scheme or artifice to defraud the plaintiffs and the public at large was conducted in personal interviews, in group interviews, via television and radio, and through the mails and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 62 of 87 PageID #: 62 via wire transmissions, including the Internet.

- 264. In approximately late 2001/early 2002, defendants launched an International Patient Program, whereby they targeted Europeans, and predominately Italian nationals, in Italy, for Fractionated Stereotactic Radiosurgery treatment for various types of cancer.
- 265. The defendants, on the Internet and in their marketing kit, defined Fractionated Stereotactic Radiosurgery as "... precision radiation using multiple, finely contoured beams from many different angles all directed at the cancer, minimizing radiation to normal healthy tissue. A non-invasive stereotactic frame maintains the body in a stable, reproducible position. A stereotactic body frame secures this position which is painlessly and non-invasively custom-molded about the body."
- 266. The hospital and physician defendants, with the advice, consent, encouragement and complicity of the other defendants, rendered futile, unproductive, and ineffectual Fractionated Stereotactic Radiosurgery to hundreds of Italian nationals, including the plaintiffs herein, between May 2002 and 2003.
- 267. Upon information and belief, in late 2003 or early 2004 Fractionated Stereotactic Radiosurgery treatment was suspended by the defendants, although the defendant LEDERMAN continues to advertise such treatment at Cabrini Medical Center, in Manhattan.
- 268. The defendants, individually and acting in concert, promoted, marketed, and advertised their stereotactic radiosurgery treatment to Italian nationals in Italy, including the plaintiffs.
- 269. The defendants employed various media to promote, market, and advertise the stereotactic radiosurgery treatment throughout Italy and the United States, including, but not limited to, printed

- 270. The defendants lured and enticed patients from the public at large, including the plaintiffs, by false, fraudulent and deceitful advertisements and misrepresentations, including representations that the radiosurgery treatment had "tremendous results" with extraordinary and enticingly high success rates for various forms of cancer.
- 271. The defendants printed and disseminated by the mails and various electronic media written materials regarding their program, including the booklet "Fractionated Stereotactic Body Radiosurgery at Staten Island University Hospital."
- 272. The defendants made false and misleading statements in these written materials to deceive the public at large and prospective patients, including the plaintiffs, and to entice them to participate in their stereotactic radiosurgery program at SIUH.
- 273. The defendants made the following misleading, fraudulent, described, and shocking claims, statements, and information in their "Fractionated Stereotactic Body Radiosurgery" marketing booklet:

"Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery - 90 percent - are successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."

"The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area - meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."

"Many patients were so-called 'hopeless cases' before coming to Staten Island University Hospital."

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 64 of 87 PageID #: 64 The booklet then continues with the following outrageous, misleading and false representations:

"Primary Liver Cancers: ... In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90 percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."

"Liver Metastases: ... We have a success rate of 88 percent ..."

"Primary Lung Carcinomas: ... The local control rate is 89 percent."

"Pulmonary or Lung Metastases: ... The local control rate is 88 percent. Many patients come to us with severe lung disease not felt to be candidates for standard surgery or radiation."

"Primary Pancreas Cancers: Primary pancreas cancers have been treated with a very high rate of success. In fact, 94 percent of primary pancreas cancers currently have been successfully controlled in the treated area with Body Radiosurgery at Staten Island University Hospital. Many included patients who had extensive prior unsuccessful treatment ... Furthermore, the size of the cancers treated with Body Radiosurgery here was, on average, three times the size and still we had a dramatically higher success rate. Thus, our success rate locally for pancreas cancers is 94 percent."

"Other Abdominal Tumors: ... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as adrenal glands and pre-sacral metastases. The local control rate for adrenal tumors is 94 percent."

- 274. The plaintiffs also relied on the following misinformation disseminated by the defendants:
 - (a) "Our group of expert physicians has the greatest experience worldwide."
 - (b) "Staten Island University Hospital has led the way with refined development of non-invasive techniques for Fractionated Stereotactic Radiosurgery treating brain and body tumors. We have performed one hundred thousand radiosurgeries! Results are superior for many tumors benign and malignant with better maintenance of function, fewer complications and lesser need

- (c) "Fractionated Stereotactic Radiosurgery...
 Often it can be used initially at the time of
 diagnosis and, if necessary, later, if standard
 surgery, chemotherapy or radiation has not
 been fully effective."
- (d) "We have superb results in controlling targeted tumors even when normal radiation has not been successful..."
- (e) "...higher doses of radiation can be delivered to the cancer with anticipation of greater success."
- (f) "Indeed, the vast majority of cancer treatments at Staten Island University Hospital with Body Radiosurgery 90 percent are successful in the targeted area. Success means the cancer in the treatment field stops growing, shrinks or disappears. This is the control rate for the remainder of the patient's life, not just weeks or months, which is usually how chemotherapy is judged. That is markedly different than radiation elsewhere."
- (g) "The vast majority of cancers (primary as well as metastatic) treated at Staten Island University Hospital are treated successfully in the targeted area meaning cessation of growth, shrinkage or disappearance of the cancer. Some cancers were treated only with Body Radiosurgery while others had extensive prior surgery, chemotherapy and/or standard radiation therapy."
- (h) "Indeed, more than one hundred thousand stereotactic radiosurgery procedures have been performed at Staten Island University Hospital over many years."
- (i) "Out CT simulator used for imaging is considered one of the finest worldwide - to allow us better visualization of the cancer. Few centers have access to the technology we use daily."

- "(Fractionated Stereotactic Radiosurgery) radiation will be much better tolerated with superior outcomes then standard therapy, even though we give higher treatment doses, when appropriate."
- (k) "The ultimate three-dimensional radiation well beyond conformal or just intensity modulated inverse planning is part of our daily armamentarium. Conformal radiation neither has this degree of sophistication nor these results. Ours is a technique with which we are most comfortable and perform repeatedly every day and every night for patients who come from around the country and throughout the world."
- (l) "Data collected with thousands of procedures being performed continue to show marked efficacy for primary and metastatic cancer treatment. Frequently these cancers were considered to be untreatable by other modalities or to have treatment approaches that were much less promising."
- (m) "... but a vast array of types of cancers including adenocarcinomas, squamous carcinomas, lung cancers, breast cancer, germ cell tumors, primary liver tumors, pancreas tumors, colon cancers, sarcomas, melanomas, renal cell, metastatic and primary head and neck cancers and others have been successfully treated and are included in ongoing data evaluation."
- (n) "Many patients were so-called "hopcless cases" before coming to Staten Island University Hospital. Some come to Staten Island University Hospital insisting on Body Radiosurgery only - wishing not to receive any standard therapy."
- (o) "Body Radiosurgery has been successfully implemented over the years for hepatocellular and other primary liver cancers. Body Radiosurgery for primary liver tumors, such as hepatocellular carcinomas, cholangiocarcinoma and gall bladder cancers,

- (p) "In fact, many patients come to us after being considered for surgery elsewhere and refused, or were found to be inoperable at the time of surgery. The control rate of primary liver tumors is high in the treated area - meaning over 90 percent of treated tumors stopped growing, shrunk or disappeared in the treated area when evaluated by follow-up scanning."
- (q) "Liver metastases are cancers that have spread to the liver from the other primary sites... We have a success rate of 88 percent."
- (r) "...primary lung cancers can be treated with this technique... Many patients with lung cancers have chronic pulmonary obstruction disease and thus limitation of respiratory function. Because stereotactic radiosurgery minimizes the adverse effects to the healthy normal lung, one anticipates a better outcome using our pinpoint precision technique... Body Radiosurgery can be used alone or in combination after external beam radiation to boost the radiation dose to enhance success of treatment. The local control rate is 89 percent."
- "Lung metastases are cancer nodules that (s) have spread to the lung from other primary sites. Pulmonary or lung metastases have been treated with Body Radiosurgery across the spectrum in size ranging from the small to the large. Standard radiation offers little in this specific category. Most common origins include head and neck cancers, melanoma, renal cells, breast, sarcoma, gastro-intestinal, colon, pancreas, liver, germ cell cancers, thyroid, and other primarics. The local control rate is 88 percent. Many patients come to us with severe lung disease not felt to be candidates for standard surgery and radiation."
- (t) "Primary pancreas cancers have been treated with a very high rate of success. In fact, 94 percent of primary pancreas cancers currently

have been successfully controlled in the treated area with Body Radiosurgery in comparison to infusion of radioactive P32 and found Body Radiosurgery superior... Thus, our success rate locally for pancreas cancers is 94 percent."

- (u) "In the abdominal cavity, we treat primary and metastatic cancers... Size range is broad, from the very small to the very large with the overwhelmingly majority of cancers showing cessation of growth, shrinkage or complete disappearance. Excellent results have been shown for sites such as the adrenal glands and pre-sacral metastases. The local control rate for adrenal tumors is 94 percent."
- (v) "Many patients with cancers who cannot be treated successfully using standard therapy or those with cancers that have recurred despite standard chemotherapy, surgery or radiation may wish to inquire about Body Radiosurgery. Also, those wishing this innovative therapy as a boost radiation dose (after standard radiation) to increase chances of local control and overall success should be motivated to investigate Body Radiosurgery by contacting our physicians at Staten Island University Hospital."
- (w) "...Staten Island University Hospital has the ability to treat cancers extending from the head to the toc using sophisticated noninvasive techniques. These are the most advanced techniques worldwide."
- (x) "Those interested in Body Radiosurgery arc asked to send relevant information, reports and pertinent radiographic studies especially CT scans and/or MRI scans - to our Radiosurgery Center for review."
- (y) "... 85 percent more men are cancer-free in our hands at SIUH than if they had radical prostatectomy ... at Johns Hopkins ... our results compare superbly to treatment at Harvard or University of Pennsylvania with radiation, radical prostatectomy or seeds

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alone - or with hormones ... there is a 77 percent disease-free survival at Staten Island University Hospital using combined seed/body radiosurgery. That is consistent with 157 percent improvement in outcome when treated at Staten Island University Hospital. Imagine the potential saving of lives."

- 275. The printed materials also falsely claimed that the highly successful treatment had minimal side effects.
- 276. Defendants translated these written materials into the Italian language and disseminated them by the mails and various electronic media to prospective Italian cancer patients.
- 277. Defendants also created and disseminated numerous videotaped advertisements regarding their Stereotactic Body Radiosurgery program both in English and in Italian, and disseminated them to the plaintiffs and the general public in Italy, other European countries, and the United States.
- 278. These videotapes/DVDs contained the same false, fraudulent and misleading information and representations in the printed sales packages, plus other reckless, wanton representations.
- 279. One of the videotapes, "Fractionated Stereotactic Body Radiosurgery," included the following false, fraudulent, misleading, and shocking claims, statements, and information by defendant LEDERMAN:
 - "... 90% success rate. Success means cessation of growth, shrinkage, or disappearance of the cancer. It's quick-each treatment takes thirty minutes or less and patients can go home and back to their normal activities very quickly after treatment. Many people call it a treat, not a treatment because of the effectiveness and the lack of toxicity in general."

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280. At all relevant times herein, defendant LEDERMAN was the Director of Radiation

Oncology for the defendant hospitals.

281. Defendants created and disseminated a videotape entitled "The Radiosurgery Center,

Fractionated Stereotactic," which included the following false, fraudulent, misleading, and shocking

claims, statements, and information:

"This new treatment is non-invasive, highly successful, and offers

great hope to those who previously thought there was none."

"Tremendous results, results in many hopeless cases, people who thought there were no chances for them are coming, and many, many are

having chances, another break at life."

"Tremendous results," "very high success rate," and a "90% success rate" are repeatedly touted claims.

282. Defendants used numerous false, misleading, and deceitful testimonials of other cancer

patients in these videotapes to promote the stereotactic radiosurgery program.

283. Defendants promoted their stereotactic radiosurgery program on Italian television.

284. The televised broadcasts contained the same false, fraudulent and misleading information

to induce Italian cancer patients, including the plaintiffs, to leave Italy, abandon their treatment there, and

undergo treatment by the defendants in Staten Island at SIUH.

285. In addition, defendants created and launched numerous Internet websites regarding their

Stereotactic Body Radiosurgery program, both in English and Italian.

286. The Internet websites contained the same false, fraudulent and misleading information to

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 71 of 87 PageID #: 71 induce Italian cancer patients, including the plaintiffs, to leave Italy, abandon their treatment there, and undergo treatment by the defendants in Staten Island at SIUH.

- 287. The Italian Internet websites also included application instructions directing prospective cancer patients to apply to the stereotactic radiosurgery program merely by sending a CT scan, a brief clinical history, a one-hundred Euro application fee, and miscellaneous information to defendant SALVATORE CONTE.
 - 288. The defendants preyed upon the plaintiffs' fears and hopes at their most vulnerable time.
- 289. The systematic dissemination of misinformation and promotion of false hope were designed to lure vulnerable cancer patients, including the plaintiffs herein, and their loved ones, to the defendants' stereotactic radiosurgery program in Staten Island.
- 290. That any reasonable prospective patient, including the plaintiffs, would rely on this false, misleading and deceitful information and undergo the promoted stereotactic radiosurgery treatment.
 - 291. That the plaintiffs herein were in fact deceived and misled by the defendants.
- 292. That based upon the plaintiffs' reasonable reliance on the defendants' material misrepresentations, the plaintiffs herein were entitled to leave Italy and undergo treatment by the defendants in Staten Island.
 - 293. In addition, defendants planned, advertised, organized, and conducted many promotional

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 72 of 87 PageID #: 72 seminars and conferences throughout Italy, whereby the defendants reiterated the false, fraudulent, and deceitful information contained in the written materials and other media.

- 294. Defendants aggressively marketed their treatment program at these seminars and conferences to cancer patients in attendance with the same false, fraudulent, and deceitful information, and even implored them to take extra copies to distribute to other cancer victims and their families in their hometowns.
- 295. Defendants told prospective patients to bring their CT scans to the conferences for review by their agents, servants, and/or employees.
- 296. Defendant LEDERMAN spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the defendants' stereotactic radiosurgery treatment program.
- 297. Defendant SALVATORE CONTE spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the treatment program.
- 298. Defendant GELMI-NOURBAHA spoke at these conferences and reiterated the false, fraudulent and misleading information regarding the treatment program.
- 299. Defendants held out defendant SALVATORE CONTE as a medical doctor and oncologist at the conferences.
 - 300. In fact, certain of defendants' televised broadcasts contained a subscript at numerous times

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 73 of 87 PageID #: 73 while defendant SALVATORE CONTE is speaking, identifying him as a medical doctor and an oncologist.

- 301. Defendants provided defendant SALVATORE CONTE with business cards identifying him as a medical doctor and oncologist.
 - 302. That defendant SALVATORE CONTE was not a medical doctor, let alone an oncologist.
- 303. Defendants knew or should have known that defendant SALVATORE CONTE was neither a medical doctor nor an oncologist.
- 304. At the seminars and conferences, defendant LEDERMAN cursorily examined imaging films of different patients, including the plaintiffs, in attendance and told them and their families that he and the defendants could cure them.
- 305. Defendants then transmitted letters of "acceptance" to these patients, including the plaintiffs, by mail and/or facsimile transmissions.
- 306. That when plaintiffs responded to the various media advertising by the defendants and/or attended the defendants' conferences, they were then directed to meet with defendant SALVATORE CONTE for processing and initial evaluation.
- 307. Defendants established an office in Naples, Italy, for defendant SALVATORE CONTE, bearing an awning emblazened with the name Staten Island University Hospital Radiosurgery Center, to

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 74 of 87 PageID #: 74 attract and process prospective patients.

- 308. Defendants paid for all expenses in establishing defendant SALVATORE CONTE's office in Naples.
 - 309. Defendants also employed defendant PERSICO to work in the Naples office.
- 310. Defendant SALVATORE CONTE held himself out to be a physician to render medical advice and opinions.
- 311. Defendant SALVATORE CONTE, holding himself out to be a physician, met with prospective patients, including the plaintiffs herein, and interviewed them, reviewed their CT scans, and advised them that they would be cured at the defendants' facilities in New York.
- 312. Defendant SALVATORE CONTE advised the plaintiffs and other patients that he was sending their CT scans and information to the defendants in Staten Island, purportedly for review and evaluation.
- 313. The defendants in New York, upon formally accepting prospective patients into their stereotactic radiosurgery program, sent these patients, including the plaintiffs, false and misleading information by facsimile and/or mail stating that their particular case was treatable.
- 314. The defendants preyed upon the plaintiffs' fears and hopes at their most vulnerable time, when stricken with cancer.

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 75 of 87 PageID #: 75 315. The systematic dissemination of misinformation and promotion of false hope were designed

to lure vulnerable cancer patients, including the plaintiffs herein, and their loved ones, to the defendants' stereotactic radiosurgery program in New York.

- 316. The plaintiffs reasonably relied on the false, misleading and deceitful information to undergo the promoted Fractionated Stereotactic Radiosurgery treatment.
 - 317. The plaintiffs herein were in fact deceived and misled by the defendants.
- 318. Based upon the plaintiffs' reasonable reliance on the defendants' intentional, material misrepresentations, the plaintiffs were enticed to leave Italy and undergo treatment by the defendants in Staten Island, but the majority of the patients treated, including the deceased plaintiffs, died shortly after treatment, sometimes within weeks, sometimes within months.
- 319. Defendants charged each patient, including the plaintiffs herein, \$17,500.00 to enter the program, which said fee had to be paid in advance, and which did not include the plaintiffs' traveling expenses to and from Staten Island and Italy.
- 320. The defendants included with the aforementioned "acceptance letter" to the patients, including the plaintiffs herein, instruction sheets for payment, travel arrangements, and miscellaneous logistical information regarding the defendants' facilities in New York, which included a 10% payment (\$1,750.00) to be made directly to defendant SALVATORE CONTE's personal banking account by wire transfer.

- Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 76 of 87 PageID #: 76 321. The defendants negotiated this kickback with defendant SALVATORE CONTE as well as payment of his overhead expenses and office space in Naples, Italy, in consideration for his promise to meet defendants' quota for patients.
- 322. The kickback arrangement was discussed and approved at several meetings at the defendants' facilities in New York and/or in Italy among defendants consisting of at least LEDERMAN, SILVERMAN, GROSMAN, JOSEPH CONTE, SALVATORE CONTE, GELMI-NOURBAHA, and perhaps others.
- 323. The instructions also directed the patients, including the plaintiffs herein, to wire the balance of the charges to the defendant SIUH's operating account in New York.
- 324. The patients, including the plaintiffs herein, did in fact wire the balance of the charges to the defendant SIUH's operating account in New York.
- 325. In consideration of his efforts, the defendants also paid defendant LEDERMAN a set percentage of the monies received from the plaintiff's for their treatment, to wit, 20% (\$3,500.00) of the overall fee.
- 326. In some instances, the patients, including the plaintiffs herein, received instructions to wire a portion of the funds directly into defendant LEDERMAN's account in New York.
- 327. In some instances, the patients, including the plaintiffs herein, did in fact wire a separate sum into defendant LEDERMAN's account in New York.

328. Only upon full payment of the requisite fees could the patients, including the plaintiffs

herein, be processed and scheduled for treatment.

329. The hospital defendants, upon information and belief, received gross annual fees between

\$5,000,000.00 and \$10,000,000.00 during the period beginning in 2001 for radio therapy, including

stereotactic body radiosurgery, and thereby were unjustly enriched.

330. That as a result of the defendants' intentional dissemination of false, deceitful, and

misleading advertising and unconscionable self-promotion, plaintiffs sustained injuries and damages,

including bodily injury and death, psychological injury, monetary damages, lost opportunity for obtaining

treatment and/or halting treatment in Italy, undergoing futile, unsuccessful and grossly negligent treatment

at the hands of the defendants, and impaired quality of life.

331. The defendants worked to attract as many patients as possible from Italy to the International

Patient Program without adequate planning or coordination to properly evaluate, treat, and monitor these

patients.

332. The defendants undertook and rendered futile, unnecessary, and negligent treatment to

dozens of Italian nationals, including the plaintiffs herein, for many forms of cancer between 2001 and

2003.

333. The plaintiffs' arrival at the defendants' facilities was barely acknowledged by the

defendants for days at a time.

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- 334. When the patients, including the plaintiffs herein, arrived at the defendants' facilities in New York, their needs were ignored, they received inadequate treatment, and translators were not provided.
- 335. Many patients, including the plaintiffs herein, waited several days before they were seen by any hospital personnel or by the defendant doctors.
- 336. After days of frustration, many patients and their families, including the plaintiffs herein, vented their frustrations to the defendants.
- 337. The defendants responded to the deteriorating situation by threatening to return patients to Italy without treating them and using security guards to silence concerned family members who were allegedly "making too much noise" about the lack of treatment and information.
- 338. The defendants administered the futile, unproductive, and ineffectual Fractionated Stereotactic Radiosurgery treatment to the plaintiffs.
- 339. The defendants failed to adequately evaluate and diagnose the patients, including the plaintiffs herein, before administering the Fractionated Stereotactic Radiosurgery treatment.
 - 340. The defendants were negligent in the care and treatment rendered to the plaintiffs.
- 341. Defendants failed to perform their own pathology studies on patients, including the plaintiffs herein, before administering treatment.

- 342. On several occasions, defendants refused to wait for plaintiffs' pathology to clear customs before administering the treatments, and thereafter failed to conduct their own tests to confirm the condition of the patients they were about to treat.
- 343. On at least two occasions, the defendants accepted and treated two patients who did not have cancer.
- 344. The defendants violated applicable statutes, rules, regulations and/or protocol by administering stereotactic radiosurgery to patients, including the plaintiffs herein, without confirming that the patients had cancer, all of which deviates from acceptable standards of care.
- 345. The defendants treated patients, including the plaintiffs herein, when there was no reasonable benefit to be derived, and/or no reasonable expectation that their quality of life would be improved, or extended.
- 346. The defendants treated patients, including the plaintiffs herein, when there was no hope for survival or for extending their life expectancy.
- 347. The defendants treated patients, including the plaintiffs herein, in a negligent manner, deviating from accepted standards of care.
- 348. Te defendants, after luring patients to their visiting patient program, including the plaintiffs herein, failed to fulfill their promises for accommodating patients and their families during their stay and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 80 of 87 PageID #: 80 providing proper treatment and care to the patients.

- 349. The defendants failed to obtain informed consent from the patients, including the plaintiffs herein, in that they failed to provide plaintiffs with the benefits, risks, and alternatives regarding the proposed treatments, and/or providing misleading information regarding the benefits, risks, and alternatives.
- 350. The defendants systematically and repeatedly denied the patients, including the plaintiffs herein, access to and copies of their medical records, test results, films, or any documentation or information.
- 351. Even though defendants told patients, including the plaintiffs herein, that they needed to follow-up with their doctors in Italy, two to three months after their return, the defendants inexplicably ignored patients' requests, and the requests of their Italian oncologists, for their treatment records in defendants' possession.
- 352. The patients, including the plaintiffs herein, repeatedly made desperate pleas for their medical records to the defendants as their conditions rapidly deteriorated during their stay at defendants' facilities and/or upon returning to Italy, but these pleas were inexplicably ignored by the defendants.
- 353. Defendants' administration of treatment to the patients, including the plaintiffs herein, was grossly negligent, careless, futile, and unnecessary.
 - 354. Defendants knew that their administration of treatment to the patients, including the

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- 355. The patients, including the plaintiffs herein, suffered increased fatigue, weakness, nausea, vomiting, and pain, and their condition deteriorated, with increasing frequency after each administration.
- 356. The defendant doctors on occasions too numerous to specify, in response to patient complaints of pain, including the plaintiffs herein, responded falsely by telling the patients that they were "doing very well ... recovering well ... that (their) increasing pain was normal and merely demonstrated that the cancer cells were dying ...," or that they were "merely depressed."
- 357. The patients, including the plaintiffs herein, contrary to the promises made by the defendants, personally and through various advertising media, did not benefit from stereotactic radiosurgery. Indeed, the plaintiffs' deaths were hastened by the treatment, rather than enjoying a greater life expectancy, and the condition of those still living deteriorated significantly.
- 358. The defendants' actions and conduct deprived the patients, including the plaintiffs herein, from obtaining and/or continuing with necessary and appropriate care and treatment in Italy.
- 359. The majority of the patients treated, including the deceased plaintiffs, died shortly after treatment, sometimes within weeks, sometimes within months.
- 360. The defendant hospitals breached their duty to use reasonable care in hiring, training, and supervising their employees, servants, agents, representative partners and/or joint venturers and/or co-conspirators of the defendants, including members of its medical staff, and in violating state regulations,

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 82 of 87 PageID #: 82 and in conspiring to violate New York State consumer protection and public health laws, and, indeed, New York State's Penal Law, by falsely and fraudulently representing to the plaintiffs and other terminally ill cancer patients through aggressive, false advertising and fraudulent self-promotion that the defendants could cure and/or control their cancers.

- 361. During the period of time from 2001 to 2003 the defendants made the aforementioned oral and written misrepresentations of material facts, and also concealed material facts from the plaintiffs and the public at large, including the non-disclosure to the plaintiffs:
 - (a) that in 1999 the New York State Attorney General secured an agreement from the defendant SIUH to pay \$45 million (plus an additional \$39 million dollars in free services to indigent patients) to settle a Medicaid fraud case which included among the fraudulent acts the overbilling of SIUH patients;
 - (b) that since 1996 the Office of the Inspector General of the United States Department of Health and Human Services had been investigating the defendant SIUH for misrepresentations in overstating the number of residents on staff studying at SIUH, thereby resulting in an overfunding by the federal government of the hospital's graduate medical education program;
 - (c) that in 2000 the defendants GROSSMAN, LEDERMAN, and SIUH were sued for malpractice for unnecessarily administering Fractionated Stereotactic Radiosurgery to a patient (in 2004 the jury awarded \$5.5 million for the unnecessary radiosurgery); and
 - (d) that in November 2003 the defendant LEDERMAN entered into an agreement with the New York State Department of Health, which had investigated allegations of professional misconduct in connection with the defendant's treatment of George Harrison, the Beatle, for releasing information about Mr. Harrison, without Mr. Harrison's consent, resulting in a censure and a \$5,000.00 fine to the defendant LEDERMAN (notwithstanding the defendants' carlier express and implicit oral representations to the plaintiffs that the defendants' Fractionated Stereotactic Radiosurgery had been chosen by Mr. Harrison, a world famous entertainer, who could afford any treatment, any where, any time).
- 362. The defendants' material misrepresentations and concealment of material facts were made intentionally and/or with a reckless disregard for the truth, to carry out a common scheme, artifice and

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 83 of 87 PageID #: 83 fraud to unjustly enrich the defendants, at a cost to the plaintiffs of their health and very lives.

- 363. The plaintiffs reasonably and justifiably relied to their detriment on that which they believed to be the truthfulness of the defendants' representations and the defendants' full disclosure of material facts, and each plaintiff thereby was induced to pay \$17,500.00 (exclusive of round trip traveling costs and expenses to and from Italy and New York) to the defendants for the advertised living accommodations in, and Fractionated Stereotactic Radiosurgery treatment at, the defendants' hospitals in Staten Island.
- 364. The defendants' enterprise was, and continues to be, engaged in interstate and foreign commerce, to wit, the delivery of medical, hospital and healthcare services to the citizens of other states and foreign countries.
- activity, and actually engaged in that pattern of racketeering activity, by making the aforementioned intentional, fraudulent representations, by the commission of between 100 and 200 mail and wire frauds (at least twenty-seven of which were perpetrated on the plaintiffs), and by concealing material facts, and by engaging in false advertising practices, in order to defraud the plaintiffs and the public at large to induce them to purchase the defendants' Fractionated Stereotactic Radiosurgery treatment.
- 366. The fraudulently induced purchase of the Fractionated Stereotactic Radiosurgery treatment actually caused the plaintiffs to sustain injuries and damages apart from the cost paid to the defendants, including bodily and psychological injuries; loss of the opportunity to receive appropriate treatment in Italy

Case 1:04-cv-03736-ILG-RLM Document 1 Filed 08/27/04 Page 84 of 87 PageID #: 84 or elsewhere increasing the probability of length of survival with a greater quality of life; loss of the opportunity to receive systematic palliative care in Italy or elsewhere; pain and suffering; wrongful death; and loss of consortium.

- 367. The defendants, in furtherance of their scheme to defraud the plaintiffs and the public at large to carry out their pattern of racketeering activity, violated federal and state criminal laws, including false advertising, mail fraud, wire fraud, engaging in the unauthorized practice of medicine, engaging in the unauthorized use of a professional title, and aiding and abetting the defendant SALVATORE CONTE to engage in the unauthorized practice of medicine.
- 368. The pattern of racketeering activity engaged in by the defendants involved hundreds of predicate acts constituting mail fraud (18 U.S.C.A.§1341) and wire fraud (18 U.S.C.A §1343) including those committed against the nine plaintiffs herein, all of which is "racketeering activity" as defined in 18 U.S.C.A.§1961.
- 369. The plaintiffs relied upon the misrepresentations and omissions directed at them by the defendants as part of their pattern of racketeering activity, and as a direct result suffered damages to their property and persons, including death.
- 370. The defendants' conduct was knowing, intentional, with malice, demonstrating a complete lack of care in conscious disregard for the plaintiffs' rights and privileges.
- 371. The defendants' conduct was motivated by greed and an obsession with bottom line profits and profiteering.

- 372. The defendants' conduct was reckless, wilfull and wanton, with malice, demonstrating a complete want of care and attention to duty, demonstrating a complete lack of care in conscious disregard for the plaintiffs' rights and privileges.
- 373. By reason of the foregoing each plaintiff suffered compensatory damages of no less than \$10,000,000.00 together with punitive damages to be determined at trial, and an award of counsel fees and costs and disbursements.

WHEREFORE, the plaintiffs demand judgment against the defendants as follows:

- On Count I: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages, together with treble damages and an award of counsel fees and costs and disbursements.
- On Count II: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- On Count III: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- 4. On Count IV: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- On Count V: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- 6. On Count VI: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.

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- 7. On Count VII: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- 8. On Count VIII: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- On Count IX: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- 10. On Count X: Compensatory damages in an amount to be proven at trial but at least \$2,000,000.00 for each of the nine plaintiffs.
- 11. On Count XI: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages and an award of counsel fees and costs and disbursements.
- 12. On Count XII: Compensatory damages in an amount to be proven at trial but at least \$10,000,000.00 for each of the nine plaintiffs, together with punitive damages, together with treble damages and an award of counsel fees and costs and disbursements.
- 13. For such other and further relief as may be just, proper, lawful and equitable.

Dated: Staten Island, New York August 27, 2004

Respectfully submitted,

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